IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Daniel L. Dunn	Docket: 186714/US	
Application No.:	10/688,858	Confirmation No. 9455	
Filing Date:	October 17, 2003	Examiner:	Linh Giang Le
Title:	SYSTEM AND METHOD FOR ASSESSING HEALTHCARE RISKS	Group Art Unit:	3626

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF

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(i) REAL PARTY IN INTEREST

The present application has been assigned to Ingenix, a Delaware corporation.

(ii) RELATED APPEALS AND INTERFERENCES

On April 27, 2008, appellants filed a Notice of Appeal in the present application. This appeal was assigned Appeal No. 2008-4656 (the '656 appeal) and on December 3, 2008, the '656 appeal was remanded to the examiner upon request of the Office of the Group Director of Technology Center 3600. On December 9, 2008, the Examiner mailed a new Examiner's Answer including a new ground of rejection and giving the Appellants the option to either (1) Reopen prosecution or (2) Maintain appeal. On January 16, 2009, Appellants filed a response under 37 CFR § 1.111 thereby electing to reopen prosecution before the Examiner. Instead of reopening prosecution in response to appellants filing, the Examiner issued a new Examiner's Answer on July 22, 2009. This caused an additional Appeal No. 2010-001748 (the '748 appeal) to be assigned. On July 6, 2010, the '748 appeal was remanded to the Examiner to reopen prosecution. The '656 remand and the '748 remand are both attached in the Related Proceedings Appendix (x).

(iii) STATUS OF CLAIMS

Claims 1-10 are pending, and claim 1-10 are herein appealed. Claims 1-10 stand rejected under 35 U.S.C. § 103 (a) over Robertson (U.S. Patent Application Pub. No. 2004/0024620) in view of Bienvenu (2002/0188476).

(iv) STATUS OF AMENDMENTS

No claim amendments were filed subsequent to the final rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is generally directed towards a computer-implemented method for assessing the risk of insuring a healthcare patient in which a combination of demographic data (such as age and gender) and prescription data (for each prescription filled by the patient) are collected and analyzed to obtain a risk score for the patient (claim 1). An information processing system comprising a processor for performing the same method is also claimed (claim 10).

The claimed invention does not merely describe collecting demographic data and prescription data. Instead, the claimed invention recites a detailed process in which: the prescription data for each prescription is assigned to at least one risk group based upon at least one medical condition typically treated by the prescription; risk data including the risk groups for all of the patient's prescription data is stored; and a risk score is calculated for the patient based upon the patient's risk data and demographic data. By analyzing the nature and mix of demographic data and prescription data related to a patient as recited in claims 1-10, a pharmacy-based clinical profile for a patient can be generated and serve as a marker of a patient's prospective health risk. *See e.g.,* specification at page 3.

Independent claims 1 and 10 are supported by the accompanying specification as follows. Claim 1 recites "one or more computers performing the following:" and claim 10 recites "a computer processor for:" (*See e.g.,* page 3, lines 8-9). Claims 1 and 10 also recite "receiving demographic data on a patient and prescription data for each prescription filled by the patient" (*See e.g.,* page 3, lines 11-13; Fig. 1, first oval), "assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription" (*See e.g.,* page 4, lines 1-3 and page 6, line 8 to page 7, line 19; Fig. 1, step 104), "storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient" (*See e.g.,* page 3, lines 8-9 and page 6 lines 1-5), and "calculating a risk score for the patient based upon the risk data and the demographic data of the patient." (*See e.g.,* page 4, lines 11-13; page 8, line 10 to page 9 line 6; and page 10, line 14 to page 11 line 16; Fig. 1, step 112; and Fig. 4).

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-10 are unpatentable under 35 U.S.C. § 103 (a) over Robertson (U.S. Patent Application Pub. No. 2004/0024620) in view of Bienvenu (U.S. Patent Application Pub. No. 2002/0188476).

(vii) ARGUMENT

(A) PRELIMINARY STATEMENT

Appellants respectfully submit that the Examiner has not established a *prima facie* case of obviousness as to claims 1-10 because the combination of references relied on by the Examiner does not teach or suggest all the claim limitations as required under 35 U.S.C. §103(a). As discussed in detail below, neither reference teaches or suggests any of these expressly recited features of claims 1-10: assigning prescription data to risk groups based upon a medical condition treated by the prescription, storing risk data including all risk groups for the patient's prescription data, or calculating a risk score for the patient based upon the patient's risk data and demographic data.

Appellants further submit that the Examiner has not established a *prima facie* case of obviousness because the combination of references is improper.

Accordingly, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of claims 1-10.

(B) DESCRIPTION OF THE APPLIED ART

Claims 1-10 stand rejected 35 U.S.C. § 103 (a) over Robertson (U.S. Patent Application Pub. No. 2004/0024620) in view of Bienvenu (U.S. Patent Application 2002/0188476).

Robertson describes an automobile insurance risk classification methodology in which a psychological questionnaire is provided to applicants for automobile insurance to enable risk classification of the applicants. The questionnaire is designed to measure behavioral variables relating to personality traits and other personality or psychological characteristics of the individual. Robertson does not relate to health insurance or prescriptions.

Bienvenu describes a prescription data collection system. In the Bienvenu system, prescription drug history data of a patient is requested by an insurance company and provided to the insurance company by one or more pharmacy benefit managers (PBMs). The prescription history of a patient provided by each PBM may then be integrated to provide an aggregate summary of the patient's prescription history that the insurance company may use for various purposes. For example, Bienvenu suggests that the prescription data gathered using the

disclosed prescription data collection system may be used to determine the "probability that the prescription indicates a particular condition" to "provide the insurer with the likelihood that the applicant or insured has each of the conditions indicated by the prescribed drug." See ¶ 0039. Bienvenu also suggests that the collected prescription data may be used to make "an informed decision about the insurance related risks" by accepting, rejecting or affecting the individual's insurance rating "depending on the information in the individual's prescription history" using "actuarial tables and formulas." See ¶ 0043.

(C) THE SUGGESTED COMBINATION DOES NOT DISCLOSE THE PRESENT INVENTION AS CLAIMED IN THE INDEPENDENT CLAIMS

Independent claims 1 and 10 of the present application recite: (1) "assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;" (2) "storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient;" and (3) "calculating a risk score for the patient based upon the risk data and the demographic data of the patient." Robertson and Bienvenu, alone or in combination, do not teach or suggest all of the features recited in claims 1 and 10.

(1) assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;

Neither Robertson nor Bienvenu teaches or suggests this feature recited in claims 1 and 10.

Robertson teaches an automobile insurance risk assessment methodology using a questionnaire to measure personality variables of a prospective insured. Robertson says nothing of (a) prescription data or (2) assigning data to a risk group. With respect to prescription data, the Examiner acknowledges that Robertson does not disclose using prescription data for a patient. *Office Action* of December 28, 2006, page 3, line 1. With respect to assigning data to a risk group, while Robertson discusses classifying into risk groups, Robertson's discussion of risk groups involves classifying the "prospective insured" into a risk group not the respective data. *See,* ¶ 64. That is, Robertson discloses classifying a prospective insured into a risk group based

on answers to survey statements. *Id.* The statements themselves are not "assigned to a risk group." Rather, the prospective insured is classified into a risk group. In light of the additional "for each prescription" language, this distinction between classifying the "prospective insured" into a risk group as compared to "assigning the prescription data" to a risk group exemplifies an advantage of the claimed invention. That is, the claimed invention allows for "each prescription" of the prescription data, and the underlying medical condition typically treated thereby, to be grouped with prescriptions having similar clinical and risk characteristics and the groups may then be attributed with more or less weight when compared to other groups. Accordingly, even if the Robertson disclosure were to be supplemented with disclosure of prescription data for assessing insurance risk, the combination still falls short of the claimed invention because no where does Robertson discuss "assigning the prescription data . . . to at least one risk group."

Bienvenu fails to remedy the deficiencies of Robertson because Bienvenu also does not teach or suggest "assigning the prescription data . . . to at least one risk group." Bienvenu discusses the collection of prescription data for an individual from a plurality of PBM databases. Once collected, the system may determine category information and drug indication information for each drug. *See,* ¶¶38 and 42 and Fig. 5, nos. 84 (drug classifications) and 88 (drug indications). The Bienvenu system may also determine the probability that the prescription indicates a particular condition. *See* ¶39. Bienvenu also states that "expert rule systems may be incorporated within the system for providing mortality information based on the prescription drug history information." ¶39. Bienvenu also states that an "insurer may accept, reject, or affect the individual's insurance rating depending on the information in the individual's prescription history." ¶ 43. Bienvenu goes on to state, "[a]s understood by those of ordinary skill, actuarial tables and formulas are typically used to determine which of the insurance actions are taken." *Id.*

Other than providing mortality information and using actuarial tables to accept, reject, or affect insurance ratings, very little is mentioned in Bienvenu about how the prescription data and indications may be used, none of which includes "assigning the prescription data" to a risk group. Therefore, even assuming, based on a general reading of the above statements, that Bienvenu alludes to some sort of risk assessment based upon the prescription data of an

individual, the description does not teach, suggest or enable "assigning the prescription data for each prescription to at least one risk group" as recited in claims 1 and 10.

Accordingly, Robertson and Bienvenu, alone or in combination, suffer from the lack of the advantage of the claimed invention which allows for "each prescription" of the prescription data, and the underlying medical condition typically treated thereby, to be grouped with prescriptions having similar clinical and risk characteristics and the groups may then be attributed with more or less weight in a risk calculation.

Claims 1 and 10 are patentable over both Robertson and Bienvenu, alone or in combination.

(2) storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient;

Neither Robertson nor Bienvenu teach or suggest storing risk data as claimed in claims 1 and 10 because neither of the references teach or suggest the claimed risk data and, as such, cannot disclose storing the same. Risk data is not to be confused with a risk group or prescription data, but rather, "risk data includes the risk groups for all prescription data of the patient." That is, in this storing step, a collection of the risk groups for all prescription data is stored. As discussed above, neither Robertson nor Bienvenu teach or suggest assigning the prescription data to a risk group and, as such, cannot store a collection of risk groups in the form of risk data.

For at least these reasons, neither Robertson nor Bienvenu, alone or in combination teach or suggest storing risk data as claimed.

(3) calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

As discussed above, Robertson and Bienvenu, alone or in combination, do not teach or suggest the generation of risk data because the references fail to disclose the respective assigning and storing operations of the method. It simply is not the case that either Robertson or Bienvenu have a collection of risk groups where the risk groups have prescription data for each

prescription assigned to them. In the absence of risk data, a risk score cannot be calculated based on the same. Moreover, not only is the risk score calculated based on risk data, it is also calculated based on demographic data and as such, the calculation combines the effects of demographics and the effects of prescription-based risk data based on all grouped prescription data. Accordingly, the claimed invention allows for risk score to be calculated based on demographics but further including grouped prescription data. Accordingly, the claimed invention offers the advantage of, not only combining demographics with prescription data, but also individually controlling the effect of prescription data based on groups.

For at least these reasons, neither Robertson, nor Bienvenu, nor the asserted combination of the two references teaches or suggests calculating a risk score as claimed in claims 1 and 10.

Pending claims 2-9 depend from claim 1 and are patentable over the asserted combination of references for the same reasons as claim 1 and due to the additional limitations called for therein.

(D) THE COMBINATION OF THE CITED REFERENCES IS IMPROPER

In addition to failing to teach of the elements claimed in claims 1 and 10, the combination of Robertson with Bienvenu is improper because no articulated reasoning having a rational underpinning to combine the references has been provided and because improper hindsight reasoning has been used.

(1) No articulated reason with rationale underpinning

The PTO has the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. MPEP § 2142. "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (citations omitted). More recently, the U.S. Supreme Court indicated:

> When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. . . . . a patent composed of several elements is not proved obvious merely

> by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR Int'l Co. v. Teleflex, Inc., 127 S.Ct 1727, 1741 (2007). Therefore, the PTO should show at least that some objective teaching or suggestion in the prior art or knowledge generally held by one of ordinary skill would lead an individual to modify the relevant teachings of a reference *or* should identify a reason that would have prompted a person of skill in the field to combine the elements in the way claimed. *Id.* For purposes of obviousness, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The PTO should provide "an apparent reason to combine the known elements in the fashion claimed" and "this analysis should be made explicit." *KSR*, 127 S.Ct. at 1741. Section 2143 of the MPEP lists several exemplary rationales that may support a conclusion of obviousness, including, inter alia, "(G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to . . . combine prior art reference teachings to arrive at the claimed invention."

Presumably pursuant to section (G) just referenced, the Examiner argues that "[i]t would have been obvious to add this feature [of "screening prescription history of an insurance applicant"] to the Robertson method with the motivation of [1] having an effective system and method for assessing prescription drug history information stored in the databases, [2] processing the information and [3] incorporating the information in the insurance process (Bienvenu; Pg. 1, Para. 7)." *Office Action* of November 28, 2006, at page 3.

The Examiner's reasoning does not provide the required apparent reason to combine because it does not answer the question of why one of skill in the art would elect to combine the prescription drug history information with Robertson. In response to the reason of "having an effective system and method for assessing prescription drug history information stored in the databases," the question remains, but why have prescription drug history information in the first place. That is, whether it is an effective system and method is irrelevant. What is relevant is

why to consider prescription drug history information in the first place. In response to the reason of "processing the information," the same question remains. Why would one of skill in the art elect to use prescription drug history information in the first place? In response to the reason of "incorporating the information in the insurance process," the question remains, but why incorporate the information. The apparent reasoning required has not been provided and the Examiner has thus not properly relied on any of the exemplary rationales in MPEP Section 2143. The combination is improper and a prima fascia case of obviousness has not been established.

It is noted that while items (A) through (G) in MPEP Section 2143 are not exhaustive, the Examiner has also not offered any other rationale for combining the prescription drug history information with the teachings of Robertson. Without more, it appears that the Examiner has relied on improper hindsight and has used the claims as a road map in attempting to arrange prior art references that teach all of the elements of the claim.

(2) Combination is based on hindsight

Further evidencing the use of hindsight is that the combination of the teachings of Robertson with the use of prescription drug history information involves a series of logical steps one of skill in the art may make to combine the references. All of these logical steps or some similar chain of steps have been assumed to occur and none of them are supported by the art of record.

That is, Robertson teaches a risk classification methodology that relies on personality traits for classifying prospective insureds into risk groups. Presumably, in an effort to improve the system, or otherwise refine it, one of skill in the art may consider several options. He or she may consider further refining the current approach to collecting personality trait information by refining which questions to ask and how to ask them, for example. He or she may also consider conducting additional studies to improve the correlations between the personality trait information and the associated risk. He or she may also consider adding additional factors to the analysis. Other improvement steps may also be considered.

Assuming that one of skill in the art chooses, among the several options, to add more factors, he or she may then compile a list of other factors to consider. This may occur by use of

some correlation software to determine what factors may be relevant or noteworthy indications of risk for a particular type of insurance. In the context of auto insurance, these other factors may include driving records, type of car, zip code information, medical condition information, etc. and each factor may have a differing result with respect to its correlation with insurance claims in the particular type of insurance being considered. It is noted that in the context of auto insurance, malpractice of a medical professional, and worker's compensation as referenced by Robertson, the use of medical conditions to assess risk seems ancillary at best and unlikely to be highly correlative of risk in these insurance contexts.

From this analysis, one of skill in the art may then select a factor to include in the analysis. Noting, again, the unlikelihood of correlations of medical conditions to the types of insurance discussed in Robertson and assuming that he or she selects medical conditions anyway, he or she may then consider how to collect the medical condition information. That is, the improved system may include simply asking the prospective insured about their medical conditions. Alternatively, the improved system may involve acquiring the medical condition data from attending physicians. In still another alternative, the improved system may include accessing prescription data and deriving medical conditions from the prescription data.

Accordingly, to come to the conclusion that one of skill in the art should combine the teachings of Robertson with prescription history information, he or she may:

(1) Set out to improve or change the system;

(2) Determine what options are available to improve or change the system;

(3) Choose the option of adding factors to the analysis in light of several other options;

(4) Develop of a list of factors to consider adding;

(5) Determine which factor to add to the analysis;

(6) Choose to add medical condition information even when it may not be highly correlated to risk in the insurance context being improved; and

(7) Determine how to collect the medical condition information; and

(8) Choose to use prescription history information in light of several other options.

There is no evidence of record to support how or why one of skill in the art may navigate this inventive process and the only thing allowing the Examiner to get from Robertson to Bienvenu is the claim language. The combination has, thus, been based on improper hindsight reasoning.

For at least the above reasons, the combination of Robertson with Bienvenu is improper.

(E) CONCLUSION

For the reasons set forth above, Appellants respectfully request reversal of the Examiner's rejection of claims 1-10 under 35 U.S.C. § 103(a).

Should any additional fees be necessary, the Commissioner is hereby authorized to charge any fee deficiency associated with this paper or request to Deposit Account No. 04-1420.

Respectfully submitted,

DORSEY & WHITNEY LLP
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Date: 7/22/2011

By: _____
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(viii) CLAIMS APPENDIX

We claim:

1. A computer-implemented method for assessing risk of insuring a healthcare patient, the method comprising one or more computers performing the following:

receiving demographic data on a patient and prescription data for each prescription filled by the patient;

assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;

storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient; and

calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

2. The method of claim 1, wherein the step of assigning the prescription data to at least one risk group comprises using national drug codes to classify each prescription.

3. The method of claim 2, wherein the step of assigning the prescription data to at least one risk group further comprises categorizing each national drug code classification into one of a number of pharmacy risk groups.

4. The method of claim 1, further comprising defining additional member risk markers based on patient age and other characteristics known to indicate that the patient belongs to a high risk category and using the additional member risk markers to calculate the patient's risk score.

5. The method of claim 1, further comprising providing a clinical and demographic risk profile for the patient based on the patient's age, gender and a mix of clinical and demographic risk profiles and using the patient's clinical and demographic risk profile to calculate the patient's risk score.

6. The method of claim 5, further comprising providing multiple patient risk markers for

patients with pharmacy services that indicate multiple medical conditions.

7. The method of claim 1, wherein each risk group is assigned a numerical risk value based upon the patient's demographic data, and the patient's risk score is the sum of the numerical risk values of the risk groups in the patient's risk data.

8. The method of claim 7, wherein the risk score is computed using pre-determined weights and a patient's patient risk marker profile.

9. The method of claim 3, wherein the pharmacy risk groups comprise patient risk markers.

10. An information processing system comprising:

a computer processor for:

receiving demographic data on a patient and prescription data for each prescription prescribed for the patient;

assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;

storing risk data for the patient in an associated database, wherein the risk data includes the risk groups for all prescription data of the patient; and

calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

(ix) EVIDENCE APPENDIX

None.

(x) RELATED PROCEEDINGS APPENDIX

- Appeal No. 2008-4656 – Order Remanding Appeal to Examiner (2 Pages)
- Appeal No. 2010-001748 – Order Remanding Appeal to Examiner (3 Pages)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL L. DUNN and DOGU CELEBI

Appeal 2008-4656
Application 10/688,858
Technology Center 3600

Mailed: December 3, 2008

Before DALE M. SHAW, *Chief Appeals Administrator*

SHAW, *Chief Appeals Administrator.*

ORDER REMANDING APPEAL TO EXAMINER

The Office of the Group Director of Technology Center 3600, on behalf of the Director of the United States Patent and Trademark Office (USPTO), has asked that the application be remanded back to the examiner for further consideration.

Accordingly, it is hereby

ORDERED that the application is remanded to the Examiner for further consideration.

DMS/ewh

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL L. DUNN and DOGU CELEBI

Appeal 2010-001748
Application 10/688,858
Technology Center 3600

Before DALE M. SHAW, *Division 2 Support Administrator.*

ORDER REMANDING APPEAL TO EXAMINER

On April 27, 2007, Appellants filed a Notice of Appeal. On December 3, 2008, the case was remanded to the Examiner upon request of the Office of the Group Director of Technology Center 3600. On December 9, 2008, the Examiner mailed a new Examiner's Answer including a new ground of rejection and giving Appellants the option to either (1) Reopen prosecution or (2) Maintain appeal. On January 16, 2009, Appellants filed a response under 37 C.F.R. § 1.111 where the Appellants elected to reopen prosecution before the Examiner. Instead of reopening prosecution in

response to Appellants request, the Examiner issued a new Examiner's Answer on July 22, 2009.

Accordingly, it is

ORDERED that the application is remanded to the Examiner to reopen prosecution.

If there are any questions pertaining to this order, please contact the Board of Patent Appeals and Interferences at 571-272-9797.

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